UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

NATURAL RESOURCES DEFENSE COUNCIL and THE XERCES SOCIETY,

Plaintiffs,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY,

Defendant.

ECF CASE

09 Civ. 4317 (DLC) (DFE)

**DEFENDANT'S MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF ITS CROSS-MOTION FOR PARTIAL SUMMARY JUDGMENT**

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Defendant the Environmental Protection Agency ("EPA"), by its attorney Preet Bharara, United States Attorney for the Southern District of New York, respectfully submits this memorandum of law in opposition to the motion for summary judgment submitted by Plaintiffs Natural Resources Defense Council and the Xerxes Society (collectively, "Plaintiffs"),[1] and in support of its cross-motion for partial summary judgment on Counts Three and Four of the Amended Complaint ("Compl.").

## PRELIMINARY STATEMENT

Plaintiffs seek to challenge EPA's registration of pesticides containing the active ingredient spirotetramat, pursuant to the Federal Insecticide, Rodenticide, and Fungicide Act, 7 U.S.C. §§ 136-136y ("FIFRA") and its implementing regulations, on two grounds: First, Plaintiffs claim that EPA's analysis leading to the registration decisions was statutorily deficient; and second, they contend that the agency did not timely publish notices relating to these registrations in the *Federal Register*.

With respect to the substantive deficiencies Plaintiffs claim to have found in EPA's analysis and ultimate approval of the registration applications, none has merit. Specifically, Plaintiffs claim that EPA did not properly consider the risks and benefits associated with spirotetramat — particularly with respect to bees — in reaching its decision, and did not inquire sufficiently into two particular aspects of the application: spirotetramat degradation products and

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[1] In this memorandum, EPA cites to Plaintiffs' memorandum of law in support of their summary judgment motion as "Pls.' Br." Citations to the Joint Appendix, a complete set of which is being provided to the Court on a compact disc and an index to which (a slightly modified version of Exhibit B to the Colangelo Declaration submitted by Plaintiffs) is attached hereto, are given as "JA XX–YY," where XX refers to the document's number in the index, and YY refers to the page number within the document. Certain of the JA documents that are referred to most frequently by the parties in their respective briefs are attached to a declaration from Jean-David Barnea, counsel for EPA, for the Court's convenience.

the use of spirotetramat in mixtures with other pesticides. However, EPA conducted a comprehensive and thorough analysis of the risks and benefits of spirotetramat, including the potential risk to bees, and appropriately conditioned its registration on the registrant taking steps that would reduce these risks. In addition, EPA's registration decision was driven by its determination that the pesticides already on the market that had previously been approved for control of the same pests at the same use sites as spirotetramat posed much greater risks to the environment and human health, so that on a comparative basis, approval of spirotetramat would be a net environmental and health benefit. As for Plaintiffs' contentions with regard to degradation products and mixtures, Plaintiffs point to no statute, regulation, or other authority that requires EPA to consider these matters beyond the consideration it gave them during the registration process.

Indeed, by this motion, EPA hereby cross-moves for partial summary judgment on the two counts of Plaintiffs' amended complaint that allege deficiencies in the agency's decisionmaking process. As detailed below, EPA engaged in a comprehensive and detailed examination of spirotetramat, in collaboration with coordinate agencies from Canada and Austria, and painstakingly examined the benefits and risks associated with registration of this pesticide. Ultimately, as the administrative record shows, EPA properly decided to conditionally register spirotetramat, while requiring the registrant to submit further information and studies according to a specified timeline.

As for the missing *Federal Register* notices, EPA does not dispute that the notices were not timely published. Once the matter was brought to its attention through the filing of the instant action, however, the agency published a notice in the *Federal Register* seeking public input on the pesticide registrations in question, and is currently in the process of reviewing the responses thereto and considering what, if any, action to take in light of these comments.

Because the supposed substantive deficiencies identified by Plaintiffs have no merit, the ultimate question before the Court concerns the remedy for this procedural violation. Plaintiffs argue that the Court's only proper response should be to *vacate* the pesticide registrations — *i.e.*, command that the agency immediately rescind the manufacturer's right to market and sell the pesticide in question — and remand the matter to the agency. In light of the steps the agency has already undertaken to rectify the procedural misstep identified by Plaintiffs and the procedural rather than substantive nature of the violation, EPA believes that the correct course is for the Court to remand the matter to the agency for further proceedings *without vacating* the registrations in question. This less drastic remedy is justified both by the lack of substantive harm suffered by the Plaintiffs in light of their ability to participate in the agency's pending notice-and-comment proceedings, and by the disruption — and interference with the statutory scheme — that would be caused by outright vacatur of the registration decisions.

Thus, because Plaintiffs' only valid complaint is that the FIFRA notice-and-comment procedures were not correctly followed in this case, this Court should grant EPA partial summary judgment on Counts Three and Four of the Amended Complaint, which allege substantive deficiencies in EPA's decisionmaking process, and remand the matter to the agency for further consideration, *without vacating* the existing registrations.

## BACKGROUND

### A. The Statutory and Regulatory Scheme

"FIFRA imposes a federal licensing scheme on the sale, distribution, and use of pesticides." *Natural Res. Def. Council v. Johnson*, 461 F.3d 164, 167 (2d Cir. 2006) (citing 7 U.S.C. § 136a(a)). "The registration scheme in FIFRA requires that pesticides be licensed before they are sold or distributed." *Hardin v. Jackson*, __ F. Supp. 2d __, 2009 WL 2619217, at *1 (D.D.C. 2009) (citing 7 U.S.C. § 136a(a), (c)). "FIFRA and the implementing regulations set

forth in detail the process for registering a pesticide, including application procedures and data submission requirements." *Id.* (citing 7 U.S.C. § 136a(c) and 40 C.F.R. §§ 152.1 *et seq.*, 158.1 *et seq.*).

### *1. EPA Review of Pesticide Registration Applications*

FIFRA specifies the nature of the analysis that EPA must perform before approving a pesticide registration. Under FIFRA, EPA shall register a pesticide if it determines that the pesticide "will perform its intended function without unreasonable adverse effects on the environment" and that "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(C), (D). "Unreasonable adverse effects," in relevant part, means "any unreasonable risk to man or to the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." *Id.* § 136(bb).[2] In order to properly evaluate pesticide applications, FIFRA and its implementing regulations require registrants to submit or cite to a significant body of toxicity and exposure data for the pesticides for which they are seeking registration. *See* 7 U.S.C. § 136a(c)(2)(A) (directing EPA to publish guidelines for submissions by registrants); 40 C.F.R. §§ 158.1 *et seq.*, 161.20 *et seq.* (setting forth information to be provided by registrants).

While EPA must consider a broad range of factors in determining whether a pesticide meets this standard, the balancing of the various risks and benefits of the pesticide, and consideration of inherent policy questions, is left largely to the discretion of EPA: "[W]ithin broad limits, the [A]dministrator has latitude not merely to find facts, but also to set policy in the

[2] The definition of "unreasonable adverse effects" also includes evaluation of human dietary risk. *See id.* In this case, EPA found those risks to be acceptable, *see* JA 36, and Plaintiffs have not challenged those determinations.

public interest. Like most regulatory statutes, . . . FIFRA confers broad discretion on the [Administrator]." *Wellford v. Ruckelshaus*, 439 F.2d 598, 601 (D.C. Cir. 1971); *see also Envtl. Def. Fund v. EPA*, 465 F.2d 528, 538 (D.C. Cir. 1972) (FIFRA empowers EPA to "take account of benefits or their absence as affecting imminency of hazard").

As part of the process of EPA's approval of a pesticide registration, the agency must review and ultimately approve proposed labeling and directions for use for each pesticide. *See* 7 U.S.C. § 136a(c)(5)(B). The approved pesticide label sets forth the lawful conditions of use for a pesticide, *i.e.*, those mandated by EPA in order to ensure that the pesticide will not cause unreasonable adverse effects to human health or the environment. *See id.* § 136a(d). Indeed, it is a violation of FIFRA for any person to use a pesticide in a manner inconsistent with the EPA-approved labeling. *See id.* § 136j(a)(2)(G).

***2. FIFRA's Public Notice Requirements***

In addition to guiding the substance of EPA's analysis of pesticide registration applications, FIFRA and its implementing regulations also impose two procedural requirements on the agency relating to public notice of certain pesticide registration applications. First, FIFRA requires EPA to provide a 30-day comment period promptly after receipt of an application for, *inter alia*, registration of a pesticide containing a new active ingredient. *See* 7 U.S.C. § 136a(c)(4); *Hardin*, 2009 WL 2619217, at *1. And second, EPA has promulgated a regulation that requires it to publish a notice of issuance after granting, *inter alia*, the first registration containing a new active ingredient. *See* 40 C.F.R. § 152.102; *Hardin*, 2009 WL 2619217, at *1.

***3. Registration Decisions and Cancellation of Registration***

EPA's registrations of pesticides under FIFRA can be either unconditional or conditional. *See Hardin*, 2009 WL 2619217, at *1 (citing 7 U.S.C. § 136a(c)(5), (7)). As relevant here,

FIFRA "authorizes EPA to register a pesticide 'containing an active ingredient not contained in any currently registered pesticide' pending the receipt of certain data, provided that EPA 'determines that use of the pesticide [until the data is received] will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest.'" *Id.* (quoting 7 U.S.C. § 136a(c)(7)(C)) (alteration in original); *see also Merrell v. Thomas*, 807 F.2d 776, 779 (9th Cir. 1986) (explaining that in 1978, Congress "created [the] 'conditional registration procedure' that waived or postponed some data requirements for registering certain pesticides" (citing Federal Pesticide Act of 1978, Pub. L. No. 95-396, § 6, 92 Stat. 819, 825-26 (1978))).

"Once EPA has approved a pesticide registration, either unconditionally or conditionally, the registrant is entitled to sell the product as long as the registration remains in effect." *Hardin*, 2009 WL 2619217, at *1. However, "[o]nce registered, pesticides are still subject to continuing scrutiny by EPA." *Nat'l Coalition Against the Misuse of Pesticides v. EPA*, 867 F.2d 636, 638 (D.C. Cir. 1989) (citing 7 U.S.C. § 136d). "[A]t any time, EPA may propose cancellation of a registration and initiate elaborate cancellation proceedings if 'it appears to the Administrator that a pesticide . . . does not comply with [FIFRA] or . . . generally causes unreasonable adverse effects on the environment . . . .'" *Id.* (quoting 7 U.S.C. § 136d(b)).

The detailed FIFRA cancellation process requires consultation with the Department of Agriculture and the FIFRA Scientific Advisory Panel, and provides registrants and other adversely affected persons with the right to an administrative hearing before a cancellation becomes effective. *See* 7 U.S.C. §§ 136d(b), 136d(d), 136w(d)(1). As "an alternative to cancellation" of a pesticide registration, EPA is statutorily required to "consider restricting a pesticide's use or uses"; in determining which of these options to select, the agency must "take[] into account the impact of [its decision] on production and prices of agricultural commodities,

retail food prices, and otherwise on the agricultural economy." *Id.* § 136d(b). Unless additional "suspension" action is taken, a pesticide may continue to be sold or used during the pendency of a cancellation action. *See id.* § 136d(b)-(d); *Nat'l Coalition Against the Misuse of Pesticides*, 867 F.2d at 638. A separate provision of FIFRA subjects conditional registrations to an expedited cancellation hearing process if a registrant fails to comply with the terms of a conditional registration. *See id.* § 136d(e). Cancellation decisions are subject to review in the federal courts of appeals. *See id.* § 136n(b).

### B. EPA's Registration of Spirotetramat

EPA received three applications from Bayer CropScience, LLC and Bayer Environmental Science (collectively "Bayer" or the "registrant"), dated October 10, 2006, February 5, 2007, and April 27, 2007, to register pursuant to FIFRA pesticides containing the active ingredient spirotetramat (with brand names including Movento and Ultor) for various agricultural uses. *See* JA 44–292-97 (first registration applications); JA 47–39,322 [Envtl. Prot. Agency, *Pesticide Product Registration; Opportunity for Public Comment*, 74 Fed. Reg. 39,321, 39,322 (Aug. 6, 2009)] (hereinafter the "August 2009 *Federal Register* Notice").[3]

EPA conducted an extensive analysis of spirotetramat in collaboration with counterpart agencies in Canada and Austria. *See* JA 7–2. In this process, the agencies analyzed voluminous

[3]Bayer had also filed a petition with EPA, on the same date as the first of its FIFRA applications (October 10, 2006), for the agency to set tolerance levels for spirotetramat residues in or on agricultural commodities, pursuant to a provision of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 346a. *See* JA 1 (petition); JA 47–39,323. The agency published a notice in the *Federal Register* seeking public comment on the appropriate tolerance levels, *see* 21 U.S.C. § 346a(d)(3), on July 25, 2007. *See id.* (citing JA 5–40,879 [Envtl. Prot. Agency, *Notice of Filing of Pesticide Petitions for Residues of Pesticide Chemicals in or on Various Commodities*, 72 Fed. Reg. 40,877, 40,879 (July 25, 2007)]). After receiving and analyzing the comments thereto, EPA published a final rule on July 9, 2008 establishing tolerance levels for spirotetramat. *See id.* (citing JA 36 [Envtl. Prot. Agency, *Spirotetramat; Pesticide Tolerances*, 73 Fed. Reg. 39,251 (July 9, 2008)]).

data on such aspects of spirotetramat as its "[i]mpact on human and animal health," "[f]ate and behaviour in the environment," and its "[e]ffects on non-target organisms," *i.e.*, on animals and plants other than the pests it is intended to control. JA 7–ii; JA 7–24-73; JA 14 - JA 17. In the course of this analysis, the agencies considered hundreds of published and unpublished studies. *See* JA 8 (117-page list of studies considered).

After the conclusion of the joint agency review, EPA conducted its own further analysis of spirotetramat.[4] It conducted a comprehensive analysis of the pesticide's "human health risk," JA 18, as well as a multi-volume analysis of its "environmental fate and ecological risk," JA 19 - JA 28. The latter analysis delved deeply into spirotetramat's potential effects on animals, plants, soil, and water, and included detailed calculations of the pesticide's potential effects. *See* JA 20.

EPA ultimately summarized its findings in a memorandum (sometimes referred to as the agency's "Decision Document") that sets forth the agency's decision to conditionally register spirotetramat. *See* JA 31–1. The agency concluded that although a handful of data gaps still existed as to the pesticide, it was appropriate to conditionally register spirotetramat in the interim, with strict label restrictions protecting bees, while requiring the registrant to submit the missing data in short order. *See* JA 31–17-19; JA 20–12. One such missing data piece was a further "field test for pollinators," *i.e.*, bees. JA 31–18.

Thus, the agency issued registration notices to Bayer — in a series of four decisions dated June 30, 3008, August 8, 2008, September 24, 2008, and December 16, 2008 — granted conditional product registrations for the pesticide, which required the registrant to provide the missing data and conduct several additional studies within a strict timeline, or else be subject to

[4]The agency's review of spirotetramat was expedited based on a finding that the pesticide carried a "reduced risk" to human health and the environment compared to other pesticide chemicals presently in the market. *See* JA 3 - JA 4.

expedited cancellation pursuant to 40 C.F.R. § 136d(e). *See* JA 32–1-2; *see also* JA 34, JA 38, JA 40, JA 42.[5] As relevant here, EPA required the registrant to conduct a follow-up study, jointly designed with the appropriate division within EPA, that will study the effect of chronic exposure to spirotetramat on bees and bee larvae, which must be completed by June 2010. *See* JA 32–1-2.[6]

As noted, during the pendency of these studies, the agency put in place label warnings and special restrictions on the use of spirotetramat on plants that might attract bees. The agency concluded that these restrictions "will provide adequate protection for pollinators," *i.e.*, bees, at least during the pendency of the requested additional studies. JA 18A–107. EPA thus required that all labels for end-use pesticide products containing spirotetramat include the following warning language:

> This product is potentially toxic to honey bee larvae through residues in pollen and nectar, but not to adult honey bees. Exposure of adult bees to direct treatment or residues on blooming crops can lead to effects on honey bee larvae. See the "Directions for Use" section of this label for specific crop application instructions that minimize risk to honey bee larvae.

JA 20–12. Most significantly, EPA required the registrant to include federally enforceable use limitations in the "Directions for Use" sections of all labels for end-use pesticides containing spirotetramat that prohibit use of the pesticide on certain plants within specified time limits

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[5]The first of these approvals was for the spirotetramat "technical" registration, and the three later decisions were for spirotetramat-based "end-use" products. As one court has explained this distinction, "[a] 'technical registration' is required to . . . manufacture [a pesticide chemical], and an 'end-use' registration is required to distribute products formulated from [the pesticide chemical]." *Amvac Chem. Corp. v. Termilind, Ltd.*, No. CIV. 96-1580-HA, 1999 WL 1279664, at *1 (D. Or. Aug. 3, 1999); *see* 40 C.F.R. § 152.3.

[6]Although EPA did not publish a notice regarding its registration decision in the *Federal Register*, it did publish a 74-page summary of its decision, known as a "Pesticide Fact Sheet" — which included its findings as to bees and the requested additional studies — on its public website in June 2008, at the same time it rendered its decision. *See* JA 29.

before and after the plants produce flowers — *i.e.*, when they may attract bees. *See, e.g.*, JA 35–9 (for citrus fruits: "Do not apply this product within 10 days prior to bloom, during bloom, or until petal fall is complete."). These restrictions address the risk to bees identified by the agency. *See* JA 20–77 ("[S]pirotetramat has the potential to affect honey bee broods . . . on flowering crops, *specifically after application to the crop at bloom or up to 5 days prior to bloom* . . . ." (emphasis added)).

On August 6, 2009, after the instant suit had been filed, EPA published a notice in the *Federal Register* seeking public comment on the spirotetramat FIFRA applications and registration decisions. *See* JA 47–39,321. In the notice, the agency acknowledged that it had not previously sought public input on these applications, but committed itself to "consider[] . . . all comments received," and stated that "the Agency will take appropriate action based on that consideration and issue another Federal Register notice responding to comments received." *Id.* at 39,323. The deadline for receipt of comments was September 8, 2009. *See id.* at 39,321.

EPA received five comments in response to the August 2009 notice, *see* JA 48 - JA 57, including comments from the Natural Resources Defense Council ("NRDC"), one of the Plaintiffs in this case, *see* JA 56 - JA 57; the registrant, Bayer, *see* JA 49 - JA 52; and the National Honey Bee Advisory Board, an industry group for beekeepers, *see* JA 54 - JA 55. EPA is currently considering these comments.

### C. Plaintiffs' Complaint and Amended Complaint

On May 4, 2009, after EPA had approved the spirotetramat registrations, but before it had published the August 2009 *Federal Register* Notice, Plaintiffs brought the instant suit. The initial complaint correctly pointed out that EPA had not published *Federal Register* notices at the time it received and approved the spirotetramat registrations. Plaintiffs amended their complaint on August 20, 2009, in light of the agency's August 2009 notice. The amended

complaint sets forth four causes of action: The first two of these allege violations of the Administrative Procedures Act, 5 U.S.C. §§ 701-706 ("APA"), and FIFRA (including its implementing regulations) in EPA's failure to publish notices in the *Federal Register* upon receiving the applications for spirotetramat registration and their approval. *See* Compl. ¶¶ 28-29. The third cause of action alleges that EPA approved spirotetramat "without taking into account the economic, social, and environmental costs and benefits of the use of the pesticide." *Id.* ¶ 30. The fourth and final cause of action alleges that EPA approved the pesticide "without making the safety finding required by law, and without conducting the complete scientific review necessary to support a safety finding." *Id.* ¶ 31.

## ARGUMENT

### I. STANDARD OF REVIEW

A court's review of EPA's compliance with the provisions of FIFRA is governed by the standards set forth in the APA. *See, e.g.*, *W. Harlem Envtl. Action v. EPA*, 380 F. Supp. 2d 289, 293-94 (S.D.N.Y. 2005). Such a review is "'extremely narrow,'" *Chauffeur's Training Sch., Inc. v. Spellings*, 478 F.3d 117, 130 (2d Cir. 2007) (quoting *U.S. Postal Serv. v. Gregory*, 534 U.S. 1, 7 (2001)); a court may reverse an agency action only if it was "'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law,'" *Fund for Animals v. Kempthorne*, 538 F.3d 124, 131 (2d Cir. 2008) (quoting 5 U.S.C. § 706(2)(A)).

"[An] agency's action should only be set aside [if] it 'relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the products of expertise.'" *Id.* (quoting *Cellular Phone Taskforce v. FCC*, 205 F.3d 82, 90 (2d Cir. 2000), in turn quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). "In

evaluating agency reasoning, [a court] must be satisfied that the agency examined the relevant data and established a 'rational connection between the facts found and the choice made.'" *Id.* (quoting *State Farm*, 463 U.S. at 43). "[S]o long as the agency examines the relevant data and has set out a satisfactory explanation including a rational connection between the facts found and the choice made, a reviewing court will uphold the agency action, even a decision that is not perfectly clear, provided the agency's path to its conclusion may reasonably be discerned." *Karpova v. Snow*, 497 F.3d 262, 268 (2d Cir. 2007).

A court should grant summary judgment when "there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c)). In determining whether there is a genuine issue as to a material fact, all justifiable inferences must be drawn in favor of the non-movant. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). *Cf. Buckingham Twp. v. Wykle*, 157 F. Supp. 2d 457, 462 (E.D. Pa. 2001) (noting that "[t]here are thus generally no genuine issues of material fact in an APA case"); *cf. also Alliance to Save the Mattaponi v. U.S. Army Corps of Eng'rs*, 606 F. Supp. 2d 121, 127-28 (D.D.C. 2009) ("In a case involving review of a final agency action under the APA, . . . the standard set forth in Rule 56(c) does not apply because of the limited role of a court in reviewing the administrative record. Under the APA, it is the role of the agency to resolve factual issues to arrive at a decision that is supported by the administrative record, whereas the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did." (citations, internal quotation marks, and brackets omitted)).

## II. EPA'S DECISIONMAKING IN APPROVING THE SPIROTETRAMAT REGISTRATIONS COMPORTED WITH ALL STATUTORY AND REGULATORY REQUIREMENTS

As summarized above, *see supra* at 8-10, EPA conducted an extensive analysis of spirotetramat, a large part of which was done in collaboration with counterpart agencies in Canada and Austria. *See* JA 7–2. This analysis encompassed all aspects of spirotetramat, and focused extensively on the pesticide's potential effects on animals, plants soil, and water. *See, e.g.*, JA 20. EPA carefully documented any gaps in the data it considered, *see* JA 31–17-19, and conditioned its registration of spirotetramat on satisfactory submission by the registrant of all missing data — including a field test for bee toxicity — within a specified time period, *see* JA 32–1-2. It further mandated a warning on the label and imposed restrictions on the use of spirotetramat to minimize any potential negative effects on bees, at least during the pendency of the contemplated studies. *See* JA 20–12; JA 18A–107; JA 35–9.

In conducting this analysis, and ultimately conditionally registering spirotetramat, the agency fully discharged its duties under FIFRA to register pesticides that "perform [their] intended function without unreasonable adverse effects on the environment" and that "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(C), (D).

Plaintiffs challenge two aspects of the substance of EPA's decisions to register spirotetramat: they claim that the agency did not consider and appropriately balance the pesticide's risks and benefits, *see* Pls.' Br. 9-13; and they claim that EPA lacked sufficient information about certain matters related to spirotetramat in order to be able to properly determine whether the registrations should be granted, *see id.* at 13-17. Neither of these objections has merit.

### A. EPA Properly Considered and Weighed the Risks and Benefits of Spirotetramat

Contrary to Plaintiffs' assertions, EPA considered a large body of data regarding spirotetramat's effects on (among other things) bees; thoroughly evaluated the potential risks and uncertainties posed by its review of that data; imposed conditions on registration — requiring submission of further testing data within 24 months of registration and imposing directions-for-use restrictions on the label — in order to mitigate the identified risks; and finally weighed the risks and benefits of registering spirotetramat in light of the relative ecological and human health risks posed by the registered alternative pesticides.

#### *1. EPA Evaluated the Risks and Uncertainties of Spirotetramat to Bees*

EPA's Environmental Fate and Ecological Risk Assessment concerning spirotetramat included numerous studies regarding spirotetramat's potential effect on pollinators, including honey bees. *See* JA 20. Specifically, this risk assessment evaluated spirotetramat's potential harm to bees, finding that acutely exposing adult bees to spirotetramat did not produce significant mortality to the exposed adult bees, but that exposing adult bees to spirotetramat could be toxic to the development of bee larvae when the adults returned to the hive. *See* JA 20–76 (finding, in the latter scenario, evidence of "significant brood effects including increased mortality in adults and pupae, massive perturbation of brood development, and early brood termination"). The Risk Assessment went on to describe and evaluate the three field studies that had been conducted using spirotetramat with bees in agricultural settings, which supported this conclusion. *See* JA 20–76-77.

EPA noted that one of Bayer's submitted studies tested a lower dose of spirotetramat than required under EPA guidelines, and deviated from the guidelines in a few other respects. *See id.* The problems with this study were such that the appropriate statistical analysis could not be

performed using its results. *See id.* The agency decided that the study was nevertheless worth considering: it had been conducted using a spirotetramat dose that approximated actual expected use (it employed "use rates similar to those proposed for field use in the USA") — if not the anticipated maximum doses that must normally be tested (here, approximately twice as high) — but its limitations were nevertheless fully acknowledged. *Id.*; *see also* JA 20–12.

On the basis of these studies, EPA concluded that "although spirotetramat is not classified as highly acutely toxic to honey bees based on laboratory acute contact and oral toxicity tests, results of brood feeding studies and tunnel tests suggest the potential for effects to broods following spirotetramat applications." JA 20–77. The agency thus appropriately recognized a potential risk to bees (and in particular bee broods) from the proposed use of spirotetramat, and further recognized the uncertainties due both to the Bayer study design and inherent limitations in field testing. *See id.*

#### *2. EPA Considered, and Ultimately Approved, Conditions on Spirotetramat Registration to Minimize the Risks to Bees*

In order to mitigate the identified risks to bees and the uncertainties it identified in the testing data, EPA considered, and ultimately approved, two conditions on spirotetramat registration: (a) additional testing to address remaining uncertainties related to the field tests, and (b) use restrictions on the label to minimize negative effects on bees.

##### *a. Additional Testing*

In evaluating the Bayer field study of spirotetramat, EPA assessed whether the study complied with its April 1996 guidelines on "Field Testing for Pollinators," which sets forth detailed requirements for such studies. *See* JA 20–12 (citing Envtl. Prot. Agency, Off. of Prevention, Pesticides & Toxic Substances, *Ecological Effects Test Guidelines, OPPTS 850.3040, Field Testing for Pollinators* (Apr. 1996), *available at* http://www.epa.gov/opptsfrs/publications/

OPPTS_Harmonized/850_Ecological_Effects_Test_Guidelines/Drafts/850-3040.pdf; *see also* 40 C.F.R. § 158.630(d) (conditionally requiring testing in compliance with this guideline). The agency reviewed the discrepancies it had identified in the study — the lower dose and the lack of statistical usability — in detail. *See* JA 20–12. Because of these uncertainties, EPA recommended "that a study design" for a new study on chronic bee toxicity "be developed in collaboration with the [agency's] Environmental Fate and Effects Division," and then performed by Bayer. *Id.*

In the agency's final decision memorandum, this recommendation is adopted. *See* JA 31–19. Thus, the actual "Notice of Registration for Spirotetramat Technical," dated June 30, 2008, states:

> This product is conditionally registered . . . provided that you [Bayer]: . . .
> 3. Submit the following data: . . .
> d. Field Testing for Pollinators (OPPTS Guidelines 850.3040). A study design must be developed in collaboration with the Environmental Fate and Effects Division. Refer to the risk assessment document for details. This study must be submitted within 24 months from the date of this Notice. . . . If these conditions are not complied with, the registration will be subject to cancellation in accordance with [7 U.S.C. § 136d].

JA 32–1-2. The deadline for the registrant to submit this supplemental study is June 30, 2010.

*b. Label Restrictions Required to Protect Bees*

In order to protect bees from potential harm during the pendency of the study, EPA further required interim use restrictions to be listed on the labels for spirotetramat pesticides. The agency's Risk Assessment recommended that "[i]n the interim" until the new study is completed and can be evaluated, spirotetramat labels contain "the following protective pollinator label language":

> This product is potentially toxic to honey bee larvae through residues in pollen and nectar, but not to adult honey bees. Exposure of adult bees to direct treatment or residues on blooming crops can lead to effects on honey bee larvae. *See the*

> *"Directions for Use" section of this label for specific crop application instructions that minimize risk to honey bee larvae*.

JA 20–12 (quotation marks omitted) (emphasis added); *accord* JA 19–4. The approved end-use product labels currently in use for spirotetramat pesticide products do, in fact, carry precisely this warning. *See, e.g.*, JA 35–4 (Movento label).

In consultation with Bayer, EPA thus developed specific instructions for applying spirotetramat to particular crop types when flowers are blooming (and thus when bees may be foraging, *see* JA 20–77) in order to avoid or minimize risk to bee larvae, to be listed in the "Directions for Use" section of the labels. EPA concluded that these mandatory use restrictions "will provide adequate protection for pollinators," *i.e.*, bees, during the pendency of the additional studies. JA 18A–107. These crop-specific restrictions were designed to "give[] very specific, unambiguous directions to the applicators to protect the crops important for bees." JA 18A–105-06. For example, with regard to citrus fruits, the instructions provide: "Do not apply this product within 10 days prior to bloom, during bloom, or until petal fall is complete." JA 35–9. Appropriate crop-specific language is also included for each other crop type for which spirotetramat was approved. *See, e.g.*, JA 35–10 (for "pome fruits" including apples and pears, "apply no earlier than petal fall").

#### *3. EPA Weighed the Risks of Spirotetramat Registration Against Its Benefits*

Plaintiffs also assert that "[i]n the thousands of pages that compose the record, the only place where EPA alludes to its performance of a risk-benefit analysis is in the post hoc Federal Register notice published on August 6, 2009." Pls.' Br. 12-13. But this assertion is plainly incorrect. In its June 23, 2008 Decision Document, EPA concluded that "it is in the public interest to register spirotetramat products" because the agency had classified spirotetramat as "a 'reduced risk' pesticide" when used on particular crops in the approved manner, especially as

compared to the pesticides that were already approved for use on those crop types. JA 31–20; *see also* JA 3 - JA 4 (making the "reduced risk" determination):

> On January 16, 2007, the Reduced Risk Committee completed its review . . . and granted reduced risk status to the above uses of spirotetramat. *Compared to registered alternatives (especially carbamates and organophosphates), spirotetramat appears to have a more favorable risk profile in terms of both human health and the environment*. Spirotetramat exhibits lower acute and chronic toxicity than most registered alternatives, and does not show evidence of carcinogenicity or neurotoxicity. Spirotetramat rapidly degrades in the environment and its low use rates will result in a lower chemical load to the environment. Spirotetramat also represents a new mode of action for several of the pests on these crops, so will fit in well with resistance management strategies, potentially extending the market lifespan of other "reduced risk" chemistries currently being used to control these pests on these crops.

JA 4–1 (emphasis added); *see also* JA 3–10 (chart considered by Reduced Risk Committee comparing the "[e]cological [r]isk[s]" for spirotetramat and 18 other pesticides and suggesting that spirotetramat's risk profile is significantly better than those of the other pesticides).[7] Put simply, EPA's determination that use of spirotetramat poses less risk to the environment and to human health than use of the registered alternatives is the very risk-benefit analysis Plaintiffs complain that the agency did not perform. *See* Pls.' Br. 10 (citing *Wash. Toxics Coal. v. EPA*, 413 F.3d 1024, 1032 (9th Cir. 2005)).

### B. Despite Plaintiffs' Claims, No Further Consideration by EPA of Spirotetramat Degradates or Mixtures Is Required

Plaintiffs further argue that EPA failed to conduct a sufficient analysis of two specific aspects of spirotetramat before granting the conditional registration: an analysis of spirotetramat-enol, a product that results when the spirotetramat molecule breaks down over time (known as a "degradate"), *see* Pls.' Br. 15-16, and an evaluation of the risks involved if users mix

[7]The far-right column of this chart reviews the risks of the listed pesticides to bees, in terms of the median lethal dose (or "$LD_{50}$"), with color-coding (from green to yellow to red) corresponding to escalating EPA "Level[s] of Concern." *See* JA 3–1, 5, 10.

spirotetramat-based pesticides with other pesticides, *see id.* at 16-17. In support of their arguments, Plaintiffs cite only to one case from the Western District of Washington that, they say, requires such consideration. *See id.* at 15-16 (citing *Wash. Toxics Coal. v. U.S. Dep't of Interior*, 457 F. Supp. 2d 1158 (W.D. Wash. 2006)). Even a cursory look at this case — which has been criticized for being insufficiently deferential to agency decisionmaking, *see Defenders of Wildlife v. Kempthorne*, No. 04-1230 (GK), 2006 WL 2844232, at *19 n.15 (D.D.C. Sept. 29, 2006) — shows that it says nothing of the sort.

The *Washington Toxics* case involved a challenge to regulations promulgated by the Fish and Wildlife Service and the National Marine Fisheries Service (collectively the "Services"), regarding their obligations to enforce the Endangered Species Act, 16 U.S.C. § 1531 *et seq.* ("ESA"). Through these regulations, the Services essentially delegated their responsibilities to make certain endangered species determinations to EPA, which considers the impact of pesticides on endangered species when it registers them pursuant to FIFRA. *See Wash. Toxics*, 457 F. Supp. 2d at 1166. The case turned in relevant part on whether EPA's analysis under FIFRA was largely equivalent to that required of the Services pursuant to the ESA. *See id.* at 1182-83. The court concluded that it was not, and struck down the regulations, but made no inquiry or findings whatsoever regarding whether EPA's assessments comport with the requirements of FIFRA. *See id.* at 1182-94.[8]

Plaintiffs thus identify no statute, regulation or other authority that requires EPA to consider any factors beyond those it actually reviewed, or to require any further information

[8]Notably, even in the context of its ESA discussion, the case says nothing about testing the effects of pesticides used "in mixtures and in combination with other pesticides," as suggested by Plaintiffs, Pls.' Br. 16; rather, it speaks only of mixtures that develop over time by adding a new pesticide over "background concentrations of other pesticides" that are present from previous use, *Wash. Toxics*, 457 F. Supp. 2d at 1185.

from the registrant, relating to pesticide degradates or mixtures. FIFRA's regulations — which were themselves the product of notice-and-comment rulemaking — spell out in detail the data requirements for registration of pesticides. *See* 40 C.F.R. §§ 158.1 *et seq.*, 161.20 *et seq.* In the absence of any judicial or administrative authority requiring EPA to alter its publicly announced risk-assessment practices, it is not arbitrary and capricious for the agency to apply its existing data requirements, as it did here, in making its determination pursuant to FIFRA.

In any event, EPA did consider the "toxicity of spirotetramat enol, a major degradate . . . of spirotetramat," despite Plaintiffs' suggestion to the contrary. Pls.' Br. 15. Although Plaintiffs correctly note that EPA identified an "uncertainty regarding the risk to *terrestrial* organisms from exposure to this major degradate," JA 3–2 (emphasis added), they ignore the agency's assessment of the available data, from which EPA concluded that the toxicity to terrestrial organisms "appears to be low," JA 20–16-17 (reviewing the studies of the potential toxicity of spirotetramat-enol and other degradates on a variety of terrestrial and aquatic organisms, and concluding that "based on the currently available data, the overall toxicity of both [spirotetramat] and [its] degradates to . . . terrestrial organisms appears to be low"). Moreover, as an additional precaution in light of the uncertainties as to the toxicity of spirotetramat-enol, EPA's analysis proceeded under the assumption that the degradate in question had the same toxicity as regular spirotetramat, *see* JA 31–11 ("[T]his assessment conservatively assumed equivalent toxicity among [spirotetramat and spirotetramat-enol] and included the two [compounds] in exposure modeling and subsequent risk calculations."), an assumption with which Plaintiffs provide no reason to quarrel.

As for mixtures of spirotetramat and other pesticides, the approved labels for spirotetramat products do not approve of all such combinations, as Plaintiffs suggest; instead, the labels caution that such combinations may "create[] very unique and adverse chemical reactions,

resulting in high risk circumstances," note that "[i]t is impossible to determine physical, biological, and plant compatibility for all scenarios that may be encountered," and "recommend[] that potential users determine the chemical, physical, biological and plant compatibility of such mixes prior to applications on a broad commercial scale." JA 43–5. The labels further recommend consulting with various sources to determine whether such a combination has been successfully used before, and in the event of a proposed novel mixture, state that the user "should conduct a test to determine physical compatibility" between the ingredients to be mixed, and provides instructions on how to conduct such a test. *Id.*

Ultimately, EPA conducted a comprehensive and appropriate review of spirotetramat, including its potential toxicity to bees and bee larvae, and appropriately concluded that the pesticide could be conditionally registered pending the submission of further data to the agency. The supposed deficiencies identified by Plaintiffs in the agency's decisionmaking are illusory. For these reasons, the Court should deny Plaintiffs' motion for summary judgment on Counts Three and Four of their complaint, and grant EPA's cross-motion for summary judgment on these counts.

## III. THIS COURT SHOULD REMAND THE MATTER TO THE AGENCY WITHOUT VACATING THE EXISTING REGISTRATIONS

With respect to Counts One and Two of the complaint, there is no dispute on those Counts that EPA did not publish the required notices in the *Federal Register*. Thus, the only question is the appropriate remedy. Plaintiffs incorrectly argue that the Court must vacate EPA's decisions approving the spirotetramat registrations and remand the matter to the agency for further action. *See* Pls.' Br. 17. However, that is not the only — or, in this case, the most appropriate — remedy.

The Court has the discretion to remand the matter to the agency *without vacating* the existing registrations, and should exercise that discretion in this case not to vacate them. *See, e.g.*, *Advocates for Highway & Auto Safety v. Fed. Motor Carrier Safety Admin.*, 429 F.3d 1136, 1151 (D.C. Cir. 2005); *MCI Telecomm. Corp. v. FCC*, 143 F.3d 606, 609 (D.C. Cir. 1998); *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1492 (D.C. Cir. 1995) (collecting cases); *Idaho Farm Bureau Fed'n v. Babbitt*, 58 F.3d 1392, 1405 (9th Cir. 1995); *Chem. Mfrs. Ass'n v. EPA*, 870 F.2d 177, 236 (5th Cir. 1989); *Indep. U.S. Tanker Owners Comm. v. Dole*, 809 F.2d 847, 854-55 (D.C. Cir. 1987) (citing *Nat'l Nutritional Foods Ass'n v. Weinberger*, 512 F.2d 688, 701, 703-04 (2d Cir. 1975)) ("In fashioning a remedy for an agency's failure to present an adequate statement of basis and purpose, this court may . . . remand for specific procedures to cure the deficiency without vacating the rule . . . ."); *see generally Checkosky v. SEC*, 23 F.3d 452, 462-66 (D.C. Cir. 1994) (explaining logic behind remanding a matter to an agency without vacating its order and attaching appendix of cases in which courts have used this remedy).

Despite Plaintiffs' suggestion to the contrary, *see* Pls.' Br. at 17, courts have repeatedly remanded agency actions without vacating them in cases where, as here, the identified deficiency in the agency's action relates to public notice procedures. Thus, when EPA improperly promulgated an interpretive rule setting limits on discharge of radioactive waste — by issuing a final rule that was materially broader than the proposed rule that had been presented for public comment — the D.C. Circuit left the rule in place pending a new notice-and-comment process on the grounds that "when equity demands, an unlawfully promulgated regulation can be left in place while the agency provides the proper procedural remedy." *Fertilizer Inst. v. EPA*, 935 F.2d 1303, 1312 (D.C. Cir. 1991). The court noted that "the removal of the EPA's [rule] may affect the EPA's ability to respond adequately to serious safety hazards," *id.*, and explained that "'intervention into the process of environmental regulation, a process of great complexity,

should be accomplished with as little intrusiveness as feasible,'" *id.* (quoting *W. Oil & Gas Ass'n v. EPA*, 633 F.2d 803, 813 (9th Cir. 1980)).

Similarly, when the Farm Credit Administration ("FCA") virtually ignored 270 comments that had been submitted in response to a proposed rule, and had not addressed the substance of the petitioner's comment at all, the court explained that "[v]acatur is not necessarily indicated . . . even if an agency acts arbitrarily and capriciously in promulgating a rule." *La. Fed. Land Bank Ass'n, FLCA v. Farm Credit Admin.*, 336 F.3d 1075, 1085 (D.C. Cir. 2003) (internal quotation marks omitted). The court reasoned that "FCA will [likely] be able to justify a future decision to retain the [r]ule, inasmuch as its only error was its failure to explain what seems to be a policy difference with the plaintiffs [and] vacatur is sure to be disruptive because it would preclude a set of voluntary transactions that . . . lenders find advantageous." *Id.* (citations, brackets, and internal quotation marks omitted).

Moreover, when the Fish and Wildlife Service ("FWS") failed to provide the public the opportunity to comment on certain aspects of an endangered-species determination, the Ninth Circuit stated that "when equity demands, the regulation can be left in place while the agency follows the necessary procedures." *Idaho Farm Bureau Fed'n*, 58 F.3d at 1405. The court explained that, in addition to its concerns about the interim protection for an endangered species, "the significant expenditure of public [agency] resources, including the $400,000 spent on the [supporting] studies, would be unnecessarily wasted if we affirm the decision to set aside the listing rule when a more closely tailored remedy is available." *Id.* at 1405-06. Thus, the court found, "[t]he equitable concerns weigh toward leaving the listing rule in place while FWS remedies its procedural error and considers anew whether to list the Springs Snail." *Id.* at 1406.

Other cases applying this principle to agencies that had either failed to use notice-and-comment procedures, or had done so inadequately, abound. *See Sugar Cane Growers Coop. v.*

*Veneman*, 289 F.3d 89, 97 (D.C. Cir. 2002) (when Department of Agriculture improperly promulgated a rule governing payments to sugar growers without having conducted notice-and-comment rulemaking, court remanded the matter to the agency without vacating the rule, explaining that the "program [had already been] launched . . . . [t]he egg has been scrambled and there is no apparent way to restore the status quo ante"); *Am. Med. Ass'n v. Reno*, 57 F.3d 1129, 1135 (D.C. Cir. 1995) (when DEA set certain fees without engaging in required notice-and-comment rulemaking, court remanded without vacating the agency's action "[b]ecause of the obvious hardship that vacating the rule would impose on the agency, the likelihood that the fees collected are not grossly out of line from what they would be if accompanied by the proper explanation, and the DEA's ability to make up through future adjustment any improper overcollection."); *Chem. Mfrs. Ass'n*, 870 F.2d at 236 (remanding without vacating improperly promulgated EPA regulation setting limits on waterborne pollutants in spite of challenges by both environmental and industry groups because "the notice-and- comment proceedings may disclose that the . . . parameter urged by the NRDC is neither necessary nor feasible" and because "the industrial petitioners are not prejudiced by being subjected to . . . limitations which, if anything, may be too lenient").

The rule that emerges from these cases is that remand without vacatur is justified (1) when the deficiency in the agency's order is primarily procedural, as opposed to substantive, and/or (2) when vacating the agency's order will cause significant disruption. *See Advocates for Highway & Auto Safety*, 429 F.3d at 1151; *Sugar Cane Growers*, 289 F.3d at 98 ("[T]he decision whether to vacate depends on the seriousness of the order's deficiencies (and thus the extent of doubt whether the agency chose correctly) and the disruptive consequences of an interim change that may itself be changed." (internal quotation marks omitted)). Both of these factors are present in this case, and accordingly, remand without vacatur is warranted.

As discussed in the previous section of this memorandum, there are no substantive problems with EPA's decision to register spirotetramat — beyond the lack of public notice in the registration process. EPA properly conducted the statutorily required analysis before deciding to register the pesticide. Moreover, Plaintiffs have not been deprived of their ability to participate in the agency's decisionmaking process.[9] Indeed, Plaintiff NRDC has already submitted comments in response to EPA's August 2009 *Federal Register* Notice. *See* JA 56 - JA 57.[10] Tellingly, its comments do not advocate that spirotetramat should be entirely banned from use; instead, NRDC advocates only incrementally more strict crop-specific restrictions on spirotetramat use as well as further study on the pesticide's effects on bees and other animals (much of which NRDC acknowledges has already been requested by EPA in its conditional registration). *See* JA 57–10. NRDC's comments, along with all others received, will be

[9]If anything, Plaintiffs' ability to comment on what is now a fully developed administrative record — which was made available to the public in the docket accompanying the August 2009 *Federal Register* Notice — puts them in a somewhat improved position compared to commenting on the initial FIFRA notice, which was to be published within 30 days of the receipt of Bayer's application (and thus before most of the information about spirotetramat, or the agency's consideration of it, were available). Under FIFRA, unlike other statutes mandating notice-and-comment rulemaking, for example, public comments are to be taken at the beginning of the administrative process on not much more than the fact of the application for registration of a pesticide.

[10]Plaintiffs correctly note that the August 2009 *Federal Register* Notice and the responses thereto, discussed in this section of EPA's brief, are outside the administrative record. *See* Pls.' Br.18-20. However, because this portion of the brief discusses not the process by which EPA reached its decision, but rather the appropriate remedy for the agency's procedural violation of FIFRA, the Court may properly consider these materials in this context. *See Natural Res. Def. Council, Inc. v. U.S. Army Corps of Eng'rs*, 457 F. Supp. 2d 198, 206 (S.D.N.Y. 2006) ("For purposes of the remedy phase, a court is not limited to the administrative record. Evidence falling outside the administrative record is relevant to whether relief should be granted if such evidence shows that an agency has rectified a [statutory] violation after the onset of legal proceedings." (footnote and internal quotation marks omitted)).

considered by EPA as required by law.[11]

Vacating the registration would cause substantial disruption: because spirotetramat-based pesticides were registered by EPA over a year ago, they are now on the market for sale to growers and are in use. Removal of spirotetramat from the market may cause growers to use pesticides other than spirotetramat to treat their crops, which EPA has concluded are *more harmful* to the environment and to human health than spirotetramat. *See* JA 4–1. In EPA's view, thus, granting the relief sought by Plaintiffs may actually cause a net environmental harm. Thus, as in the *Idaho Farm Bureau* and the *Fertilizer Institute* cases, granting Plaintiffs the relief they seek may actually impair EPA's efforts at environmental protection.

In addition, the spirotetramat registration process was a multiyear process involving great expenditure of EPA resources and a international collaboration between EPA and its counterparts in Canada and Austria. *See, e.g.*, JA 7–2. For the Court to invalidate the spirotetramat registration *ab initio* might require EPA to retread largely the same path, at great expense, where a more narrowly tailored remedy is available. *See Idaho Farm Bureau*, 58 F.3d at 1405-06 (noting that "the significant expenditure of public [agency] resources, including the $400,000 spent on the [supporting] studies, would be unnecessarily wasted if we affirm the decision to set aside the listing rule when a more closely tailored remedy is available").

Moreover, to unilaterally vacate the spirotetramat registration would be to up-end the carefully balanced statutory scheme devised by Congress for cancellation of a pesticide

[11]EPA vigorously disagrees with the suggestion in Plaintiffs' brief, *see* Pls.' Br. 7-8, that its consideration of comments from the public, including NRDC, now that spirotetramat has already been registered, will differ in any material way from the consideration such comments would have received had they been submitted prior to the agency's registration decision.

registration.[12] *See supra* at 7 (describing FIFRA cancellation process). The cancellation process is designed to safeguard the potentially divergent interests of the EPA, the Department of Agriculture, growers, the general public, and the registrant, and provides each a voice and an opportunity to participate. *Cf. Merrell*, 807 F.2d at 780 ("FIFRA explicitly accommodates agriculture's need for pesticides — even environmentally risky pesticides.").

The two cases cited by Plaintiffs, in support of the dubious proposition that "EPA's failure to provide notice and comment alone warrants vacatur," illustrate why remand *without* vacatur is appropriate here. *See* Pls.' Br. 17 (citing *Heartland Reg'l Med. Ctr. v. Sebelius*, 566 F.3d 193 (D.C. Cir. 2009), and *Sprint Corp. v. FCC*, 315 F.3d 369 (D.C. Cir. 2003)). The *Heartland* decision cites *Sugar Cane Growers* in *dicta* for the proposition that a notice-and-comment violation "'normally'" leads to vacatur. 566 F.3d at 199 (quoting *Sugar Cane Growers*, 289 F.3d at 97-98). Read in the context of the *Sugar Cane Growers* decision, the statement makes sense: "normally" notice-and-comment violations should lead to vacatur, but this rule yields when the two factors discussed above — that the violation is less serious and/or that vacatur would cause undue disruption — are present, as the court found in the *Sugar Cane Growers* case itself. *See Sugar Cane Growers*, 289 F.3d at 97-98. Notably, the *Heartland* decision ultimately concluded that the rule it was considering had been previously — and correctly — remanded without vacatur. *See* 566 F.3d at 199-200. As for the *Sprint* case, the court did not ever consider whether remand without vacatur may be an appropriate remedy. Instead, the court's decision held only that the court could not *affirm* as harmless the agency's

[12]Courts have traditionally been loath to substitute a judicial forum for the elaborate administrative process set up by Congress for cancellations of pesticide registrations. *See, e.g.*, *Defenders of Wildlife*, 882 F.2d at 1299 (noting that environmental groups may not file suit under FIFRA to challenge pesticide registrations because "Congress intended that [the] FIFRA [administrative process] provide the exclusive means of cancelling a registration").

improper action — promulgating a rule without prior notice and comment. *See* 315 F.3d at 377. Here, EPA is not arguing that its error was harmless and thus that its registration decision should be upheld by this Court, but rather that its acknowledged error warrants the judicial remedy of remand without vacatur; this distinction is not addressed by the *Sprint* court.

Thus, the proper remedy for the notice-and-comment violation identified in the complaint in this case is to remand the matter to EPA for further consideration without vacating the registration of spirotetramat in the interim, pending the agency's final decision on the matter.

## CONCLUSION

For the reasons stated above, the Court should remand this matter to the Environmental Protection Agency for further consideration and should not vacate the agency's decision to register spirotetramat as a pesticide in the interim, and should grant partial summary judgment to the agency on Counts Three and Four of the Amended Complaint.

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Respectfully submitted,

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